B2. 510(k) Summary

FEB 2 8 2013

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

The Assigned 510(k) number is: K121969

1. Submitter's Identification:
   TaiDoc Technology Corporation
   3F,5F, No.127, Wugong 2nd Rd., Wugu District, New Taipei City, 24888, Taiwan

   Correspondence:
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   Regulatory Affairs Specialist
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   Date of submission: June 30th, 2012

2. Device name:
   Proprietary name: U-RIGHT Compressor Nebulizer, model TD-7013/ TD-7012

   Regulatory information:
   A. Regulation section: 21 CFR § 868.5630
   B. Classification: Class II
   C. Product Code: CAF, nebulizer (direct patient interface)
   D. Panel: Anesthesiology

3. Intended Use:
4. U-RIGHT Compressor Nebulizer, model TD-7013/ TD-7012, is designed to provide a compressed air source to aerosolize physician-prescribed liquid medication when used in combination with the packaged Nebulizer kit, *except for Pentamidine.* The packaged Nebulizer kit is intended for single use by single patient. U-RIGHT

Compressor Nebulizer, model TD-7013/ TD-7012, is intended for use with children, adolescents (2 years to 18 years old), and adult patients in the homecare settings.

5. Device Description:

U-RIGHT Compressor Nebulizer is a light weight portable aerosol nebulizer, which uses a pneumatic piston that compresses air, forcing it to flow into the nebulizer container. And the force of the air flowing into the nebulizer container disperses the liquid medicine into aerosol particles for inhalation treatment of a physician's prescription medicine.

The only difference between model TD-7012 and TD-7013 is the outer casing design. The operating principle, the compressor type, working mechanism, and the accessories Nebulizer kit are all the same in these two models.

6. Substantial Equivalence Information:

A. Predicate device name: Bestneb Portable Aerosol Therapy Unit, Model AP-10010

B. Predicate K number: K990435

C. Comparison with predicate:

The modified U-RIGHT Compressor Nebulizer has the following similarities to the predicate device:

- Same intended use
- Same patient population and same environment of use
- Same operating principle
- Same working mechanism
- Same fundamental scientific technology

The differences encompass:

- Physical appearance of unit and components
- Slight difference in storage condition
- Device weight
- Power requirement and power consumption

7. Summary of Performance Testing:

1) Aerosol Characterization Testing

The particle size distribution test via Cascade Impactor of U-RIGHT Compressor Nebulizer was performed in comparison to the predicate device K990435 with three drugs (Ipratropium bromide, Ventolin, and Cromolyn sodium). The test has shown U-RIGHT Compressor Nebulizer consistent in repeatability tests for each three classes of drug, and demonstrated equivalent performance to the predicate device K990435 that no significant difference ($p>0.05$) in the particle distributions.

U-RIGHT Compressor Nebulizer has the same performance characteristics as the predicate device and meets its product specification as well.

2) Airpath Testing

Gas sample analysis of U-RIGHT Compressor Nebulizer has performed and shown the device does not emit potential toxic gases that may cause harmful influences to human, including carbon monoxide, carbon dioxide, ozone, or volatile organic compounds (VOCs). The output of particulate matter conformed to EPA requirements of the PM2.5 standard.

3) Materials

FDA authority considers the gas path contact components the external communicating components with tissue contact. Biocompatibility evaluations of cytotoxicity (ISO 10993-5), irritation (ISO 10993-10), sensitization (ISO 10993-10), implantation (ISO 10993-6) and genotoxicity (ISO 10993-3) tests have been conducted for the gas path contact materials.

4) Safety and EMC

The electromagnetic compatibility and electric safety of the proposed device are tested to meet the following standards:

- EN 60601-1:2006
- EN 60601-1-1-2:2007, CISPR 11: 2009+A1:2010

8. Conclusion:

Based on the information provided in this submission, U-RIGHT Compressor

Nebulizer is substantially equivalent to the predicate device in safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 28, 2013

Ms. Pinjung Chen
Regulatory Affairs Specialist
TaiDoc Technology Corporation
3F,5F, No.127, Wugong 2nd Road
Wugu District
New Taipei City, Taiwan 24888

Re: K121969
Trade/Device Name: U-RIGHT Compressor Nebulizer, Model TD-7013/ TD-7012
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: II
Product Code: CAF
Dated: January 15, 2013
Received: January 22, 2013

Dear Mr. Chen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

B1. Indications for Use Statement

Indications for Use

510(k) Number: K121969

Device Name: U-RIGHT Compressor Nebulizer, Model TD-7013/ TD-7012

Indications for Use:

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Prescription Use ____X____ And/Or Over the Counter Use _____.
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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Division of Anesthesiology, General Hospital Infection Control, Dental Devices

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